

REMARKS/ARGUMENTS

Reexamination and reconsideration of this Application, withdrawal of the rejection, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the above amendments and remarks that follow.

Claims 1-28, 30-44, 46-48, and 51-60 are pending in the application. Claims 29, 45, and 49 have been cancelled without prejudice or disclaimer. Independent claims 1, 32, and 48 have been amended to recite that the administering step comprises injecting the hydrogel matrix into one or more locations selected from the group consisting of intradermal or subdermal locations beneath the ulcer, intradermal or subdermal locations at the periphery of the ulcer, and combinations thereof. Support for this amendment may be found throughout the specification and in the original claims, such as on pages 10 and 11, and in the appended examples. Additionally, support can be found in original claims 29, 45, and 49. Additionally, new claims 56-60 are presented herein. New claims 56, 58, and 60 recite specific types of ulcers. Support for the new claims can be found at the bottom of page 2 and in the middle of page 6. New claims 57 and 59 more specifically recite a preferred location for injection of the matrix. In particular, these claims recite that one or more of the injections are made in the area of the dermal/subdermal tissue junction. Support for this amendment may be found, for example, at the bottom of page 10. Applicant respectfully submits that no new matter is introduced by these amendments.

Claims 1-55 stand rejected as obvious over U.S. Patent No. 6,231,881 to Usala in view of the Miller and Mansbridge references, as well as the Davis or Pickart references. Although the Applicant continues to respectfully traverse this rejection on its merits, in order to expedite prosecution, Applicants note that U.S. Patent No. 6,231,881 is unavailable as prior art against the present application under §103(c). The '881 Usala patent is only available as a reference under §102(e) because it published after the earliest effective filing date of the present application (May 31, 2000). However, at the time the claimed invention was made, the '881 Usala patent was owned by the same person or subject to an obligation of assignment to the same person as

the present invention. Applicant directs the Examiner's attention to the assignment of U.S. Patent No. 6,231,881 to Encelle, Inc., which is recorded at Reel 009406 and Frame 0077. In addition, the present application was assigned to Encelle, Inc., as recorded at Reel 013277 and Frame 0947. Consequently, the undersigned respectfully submits, on behalf of the Assignee, that both the cited '881 patent and the present application were subject to assignment to the same person at the time the claimed invention was made. Accordingly, the '881 patent is not available as a prior art reference. For at least this reason, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claims 1-55 also stand rejected as obvious over WO 00/02999 in view of the same secondary references noted above. Although Applicant continues to believe that this rejection should be traversed on its merits, in order to expedite prosecution, it is respectfully noted that the WO 00/02999 reference is also not available as prior art. This PCT application published on January 20, 2000, which is less than a year prior to the earliest effective filing date of the present application (May 31, 2000). Accordingly, this reference is only available under §102(a).

Submitted herewith is the Declaration by Dr. Ronald Hill, who was employed at Encelle, Inc. during the general timeframe of conception and reduction to practice of the present invention and has firsthand knowledge of events related thereto. As a representative of the assignee of the present invention, Dr. Hill declares in his §1.131 Declaration that the invention embodied in the present claims was conceived and reduced to practice prior to January 20, 2000. As support for this statement, Dr. Hill refers to a study report that he prepared prior to January 20, 2000. This study describes the results of testing on diabetic ulcers on a dog, and this study is reflected in Example 1 of the present application. In this study, subcutaneous injection of a hydrogel matrix successfully treated diabetes-related ulcers in a subject. This is clear evidence of both conception and reduction to practice prior to the effective date of the cited reference. Accordingly, the WO 00/02999 reference is not available as prior art. For at least this reason, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claims 1-29, 31-42, 46-48, 50, and 51 stand rejected under the doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,261,587 in view of the Miller reference, as well as the Davis and Pickart references. Applicant continues to

believe this rejection should be traversed on the merits. However, in order to expedite allowance, independent claims 1, 32, and 48 have been amended as noted above. Specifically, these claims now recite that the hydrogel matrix is injected into one or more specific locations beneath or at the periphery of the ulcer. This recitation is similar to the description of the injection sites in claims 45 and 49. It is noted that claims 45 and 49 were not included in this rejection. It is believed that all claims are clearly distinguishable from the claims of the '587 patent, which does not describe administering hydrogel matrix by intradermal or subdermal injections beneath or at the periphery of an ulcer. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection as well.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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